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31. (Amended) A pharmaceutical dosage form comprising a gelatin capsule containing a formulation as claimed in claim 2.

### REMARKS

Claims 1-32 are pending in the application. No claim is allowed.

#### *Claim Rejections*

The telephone interview granted by Examiner Lukton on November 27, 2001 is gratefully acknowledged. During the interview, agreement was reached that amendment of claim 2 as suggested by the Examiner to delete the term "pharmaceutical" and replacing the term "an effective amount of one or more hydrophobic active ingredients" with "one or more cyclosporins" would resolve the rejection under 35 U.S.C. § 112, first paragraph. In order to expedite prosecution, and without addressing the merits of the rejection, claim 2 the present claims has been so amended. In addition, claims 2, 25, 27, 29 and 31 have been amended in accordance with the examiner's suggestions to resolve the rejections under 35 U.S.C. § 112, second paragraph.

#### *Restriction Requirement*

The Examiner's response to the Applicants' election of Group II with traverse is acknowledged. Accordingly, upon indication of allowable subject matter in Group II, Applicants respectfully request that claim 30 be joined with Group II and that the restriction between Groups I and II be withdrawn and all of the subject claims be examined.

#### *Information Disclosure Statement*

The striking of reference "M" from the Information Disclosure Statement (IDS) for lack of a translation is noted. A translation of that reference accompanies this filing together with a copy of the original PTO Form 1449. Consideration of this reference and return of the initialed Form 1449 indicating that the reference has been made or record is respectfully requested.

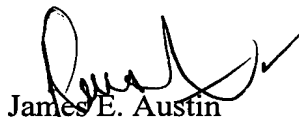
#### *Conclusion*

Accordingly, the Applicant respectfully submits that all pending claims are patentable over the cited art. Should the Examiner believe that a telephone conference would expedite the

prosecution of the present application, she is encouraged to contact the undersigned at the telephone number provided below.

If any fees are due in connection with the filing of this amendment, the Commissioner is authorized to charge such fees to Deposit Account 500388 (Order No. UDL1P049).

Respectfully submitted,  
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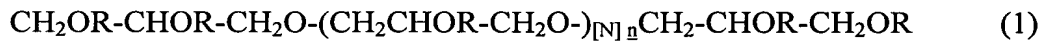
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## APPENDIX

### Marked-up copies of amended claims showing changes

2. (Twice amended) A [pharmaceutical] formulation for oral or topical administration including

- a) [an effective amount of] one or more cyclosporins [hydrophobic active ingredients];
- b) 5 to 50% of one or more compounds [selcted] selected from polyglycerol esters of fatty acids of formula (1)



wherein n is an integer from 4 to 13 and R is H or CO<sub>2</sub>R' wherein R' is C<sub>8-22</sub> saturated, unsaturated or hydroxylated alkyl and wherein at least one group R is not hydrogen;

- c) 5 to 50% of one or more compounds selected from polyglycerol esters of fatty acids and/or unsaturated fatty acids of formula (2)



wherein n is an integer from 0 –10 and R = H or CO<sub>2</sub>R'' wherein R'' is C<sub>8-22</sub> saturated, unsaturated or hydroxylated alkyl, and wherein at least one group R is not hydrogen;

- d) 5 to 50% of one or more compounds selected from the group consisting of triglyceride macrogol glycerol esters, partial glycerides of fatty acids and magrogol esters of fatty acids in which the average quantity of reacted ethylene oxide in the synthesis of these substances ranges between 50 to 150 mols and concurrently the ratio between components b) and d) is from 0.1:1 to 10:1;

wherein the above percentages are selected to total 100%;

and wherein upon dilution with water 1:1 by volume the viscosity of the formulation increases by at least 5 times in comparison to the undiluted composition.

25. (Amended) A formulation as claimed in claim 2, wherein component a) is selected from cyclosporins especially cyclosporin A, cyclosporin D or cyclosporin G, wherein the ratio of components a : c + e is 1.001 : 1 to 1.5 : 1.

27. (Amended) A formulation as claimed in claim 2, wherein component a) is selected from taxanes, especially docataxel or paclitaxel, wherein the ratio of components a : c + e is 0.001 : 1 to 1.5 : 1.

29. (Amended) A formulation as claimed in claim 2, wherein component a) includes at least one compound [substance] selected from the group comprising cyclosporins and further at least one compound [substance] selected from the group comprising taxanes.

31. (Amended) A pharmaceutical dosage form comprising a gelatin capsule containing a formulation as claimed in [any of claims] claim 2.